IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-CV-634

DEFENDANTS' OPPOSITION TO PLAINTIFF'S THIRD EMERGENCY MOTION

Early in this litigation, after this Court had stated that Sanofi's fully briefed motion for preliminary injunction "will be decided on the papers and an opinion will soon follow," *see* ECF No. 45, Sanofi inexplicably and unilaterally asked that its motion for preliminary injunction against the ADR Rule be held in abeyance. Sanofi asked the Court not to decide its motion despite HHS's explicit refusal to join that request because, as counsel for HHS explained, a preliminary injunction entered in a different judicial district that was explicitly limited to a different plaintiff would not halt the administrative dispute-resolution process against Sanofi or otherwise afford Sanofi any protection from the ADR Rule. Since that time undersigned counsel repeatedly has confirmed, both in conversations with Sanofi's counsel and in public filings in related litigation, that implementation of the dispute-resolution process challenged by Sanofi is ongoing except as to the one drug manufacturer that obtained a preliminary injunction, Eli Lilly. Now that the inevitable has occurred, Sanofi claims that changed circumstances warrant the instantaneous reviving of its previously abandoned motion and the granting of extraordinary relief under the guise of an "administrative stay." This Court should not countenance Sanofi's gamesmanship and waste of judicial and party resources; Sanofi's request

should be denied.

This is Sanofi's *third* emergency motion in litigation which, most unusually, has challenged three discrete agency actions on every conceivable ground. In February 2021 Sanofi amended its complaint to challenge HHS's recently promulgated Administrative Dispute Resolution ("ADR") Rule and that same day moved for a preliminary injunction seeking to enjoin the Rule's implementation. *See* ECF Nos. 17, 19. Although Sanofi's complaint included, among other claims, challenges to the ADR Rule under the Administrative Procedure Act, in its motion Sanofi moved for relief *only* on the grounds that the Rule violated Articles II and III of the U.S. Constitution.

The following month, this Court canceled the previously scheduled oral argument on Sanofi's fully briefed motion and indicated that the "motion will be decided on the papers and an opinion will soon follow." *See* ECF No. 45. Later that same week, a district court in the Southern District of Indiana enjoined the ADR Rule only as to a separate drug-manufacturer plaintiff, Eli Lilly, reasoning that the Rule had been promulgated without adequate notice and comment. *See* ECF No. 81, Order Granting Preliminary Injunction, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 16, 2021) ("Defendants … are hereby PRELIMINARILY ENJOINED until further order of this Court from implementing or enforcing *against Plaintiffs* the Administrative Dispute Resolution Regulations published at 85 Fed. Reg. 80,632 … .) (emphasis added). Although Sanofi had not briefed the merits of a procedural APA claim in its emergency motion, this Court directed the parties via email to file supplemental briefing related to Count IV of Sanofi's Amended Complaint, *see* ECF No. 17 at ¶¶ 102-09, and also to address the reasoning set forth in the *Eli Lilly* court's order.

HHS began preparing a supplemental brief explaining why the *Eli Lilly* court erred in enjoining the ADR Rule by imposing on the agency procedural requirements above that required by the APA. The parties concurrently negotiated a stipulated, expedited schedule for production of the administrative records and briefing cross-motions for summary judgment. *See* Ex. A (Talmor Email

Mar. 18, 2021 and attached stipulated schedule, with no request that Sanofi's motion be held in abeyance). Before that stipulation was finalized, however, counsel for Sanofi approached undersigned counsel to ask that, in light of the *Eli Lilly* court's preliminary injunction, the parties jointly ask this Court to hold in abeyance Sanofi's pending preliminary-injunction motion. Undersigned counsel explained repeatedly that the agency could not join Sanofi's request because (1) the preliminary injunction entered by a different court that was expressly limited to a different plaintiff had no bearing on agency action that might be taken against Sanofi, and (2) the agency would not suspend any agency action against Sanofi on the basis of that injunction. *See* ECF No. 79, Opp. to Mot. for Admin. Stay at 8 (explaining that HHS refused to join Sanofi's request to hold its motion in abeyance).[1] In particular, undersigned counsel clarified that the ADR process likely would move forward against Sanofi during the pendency of this litigation and expressed concern that Sanofi's request to hold its preliminary injunction motion in abeyance would waste the Court's and parties' resources if Sanofi were to later revive its motion once the ADR process was fully implemented. Sanofi nonetheless opted to move forward, confirming that it would have to decide whether to revive its motion depending on the status of these proceedings if and when the ADR process became fully implemented. These discussions resulted in a joint scheduling motion that twice confirmed that it was *Sanofi* requesting that this Court hold its emergency motion in abeyance. *See* ECF No. 46 at 2; *see also* Ex. B (Talmor Email Mar. 20, 2021, requesting change to joint motion clarifying that "Sanofi requests that … the Court hold in abeyance its motion").

In the months since, HHS has worked to implement the newly established (and statutorily mandated) administrative-dispute resolution process, while a petition against Sanofi and two other manufacturers (AstraZeneca and Eli Lilly), brought by the National Association of Community Health

[1] These events previously were explained to the Court, *see* ECF No. 79, after Sanofi inaccurately stated in its second emergency motion that the parties jointly had requested the abeyance.

Centers ("NACHC") remained pending. The status of those efforts has been publicly reported in joint status reports in related litigation in another district filed by NACHC. Specifically, in April the parties to that litigation reported that HRSA, the HHS subcomponent responsible for the 340B Program, "advised NACHC, through counsel that 'HRSA has done an initial review of your petition and determined your petition is complete.'" *See* ECF No. 14, *NACHC v. HHS*, No. 1:20-cv-3032-FYP (D.D.C. Apr. 19, 2021). Importantly, HRSA reviewed NACHC's petition and informed NACHC that it was complete *more than a month after the Lilly preliminary injunction was entered*, demonstrating that work on that petition continued. Review of NACHC's petition was the first step in adjudicating those claims. *See* https://www.hrsa.gov/opa/340badministrative-dispute-resolution (describing "the steps in the ADR Process": "Once the petition, including any supporting documentation, is received, HRSA reviews the petition for completeness and will notify the petitioner of whether the petition will move forward to the ADR Panel for review."). In April HHS also reported publicly that a package had been sent to newly confirmed Secretary Becerra recommending new appointments to the ADR Board and that, "once appointments are made, HHS *will be able to 'move forward with implementation of the current ADR Rule*,'" including NACHC's petition against Sanofi. ECF No. 14 at 4, *NACHC v. HHS* (emphasis added). On June 21, 2021, HHS publicly reported that "HHS Secretary Becerra signed a memorandum appointing ADR Board members pursuant to 42 C.F.R. § 10.20." ECF No. 16, *NACHC v. HHS*. Aside from these public representations, in recent months undersigned counsel has confirmed telephonically to counsel for Sanofi that implementation of the ADR process is ongoing. Specifically, in response to questions from Sanofi as to whether a response to NACHC's petition was due before a panel was appointed to adjudicate the petition, undersigned counsel declined to take a position and explained that Secretary Becerra's appointment of Board members allowed the HRSA Administrator to appoint a panel, at which time Sanofi could direct its questions (including on timeframes) directly to the panel.

Notwithstanding all of these clear indications that the agency has been moving forward with implementation of the ADR process, Sanofi now claims surprise and impropriety on the part of the agency for having done exactly that. Sanofi bases its claim on the fact that in August, out of an abundance of caution, HRSA asked NACHC to refile its petition against Sanofi and AstraZeneca, excluding Eli Lilly, as to whom the Rule has been enjoined. *See* ECF No. 101-3, Ex. B to Sanofi's Mot. for Admin. Stay, at 75. To be clear, HRSA did not and does not believe that proceeding to adjudicate NACHC's original petition as to Sanofi and AstraZeneca, but not Eli Lilly, would have violated the preliminary injunction entered as to Eli Lilly. HRSA determined, however, in an abundance of caution, that having NACHC refile its petition to exclude Eli Lilly would avoid any confusion or dispute on that score between the parties in *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.). NACHC's new petition maintains the same filing date as its original petition and in all ways is treated as would be the original petition. In other words, the refiling of NACHC's petition to exclude Eli Lilly was a matter of administrative convenience and did not change the legal landscape as to Sanofi, especially considering that HHS has been working to implement the ADR process and has transparently and repeatedly confirmed that that process *would move forward* during the pendency of these proceedings.

Sanofi is not entitled to an emergency "stay" of its deadline to respond to NACHC's ADR petition for multiple reasons. First and foremost, Sanofi is not entitled to emergency relief because it sat on the sidelines for months despite knowing that the agency was working to implement the ADR process *after* Sanofi unilaterally abandoned its earlier request for emergency relief *after* the parties had fully briefed its motion. True, in making its abeyance request, Sanofi unilaterally stated that it "expressly reserves the right to request that the Court rule … should it prove necessary in light of developments." ECF No. 46. But that does not justify its inexplicable choice to request that the Court *not* rule on its preliminary-injunction motion, especially given undersigned counsel's plain

representations that the process would move forward as to Sanofi. *See* ECF No. 79 at 8. Seven months later, after the Court has switched gears to decide the parties' pending cross-motions for summary judgment (which have been fully briefed since July) and the agency has worked to implement the ADR Rule, Sanofi's sudden request to resurrect its motion wastes resources of the Court and the parties.

Second, and relatedly, Sanofi's contention that changed circumstances necessitated its request rests on inaccurate premises. Sanofi claims that, "[r]emarkably, Defendant HRSA *invited* this new ADR petition to be filed against Sanofi through *ex parte* communications[2] for the open purpose of circumventing the preliminary injunction of the ADR Rule that Judge Barker granted to the manufacturer Eli Lilly." ECF No. 101-1 at 1. Sanofi even goes so far as to accuse the agency of having launched an "end run around Judge Barker's preliminary injunction," amounting to "an affront to the judicial process and a recipe for chaos." *Id.* at 15. These allegations are baseless. As set forth above, Sanofi long has known that the preliminary injunction entered by Judge Barker applied only to the plaintiff in that case and afforded Sanofi no protection from being subject to the ADR Rule. Indeed, Sanofi does not explain how it could possibly enforce against the government a preliminary injunction entered as to another plaintiff in a case to which Sanofi is not a party. Thus there is no impropriety in the agency having moved forward with the ADR process as to Sanofi; on the contrary, so long as the Rule is in effect the agency is legally obligated to implement it. Sanofi attempts to evade the consequences of its litigation choices by explaining away its abeyance request on the ground that "there was no need for this Court to rule on Sanofi's motion, because the preliminary injunction in the Lilly

[2] Sanofi repeatedly suggests that HRSA's email to NACHC constituted an improper *ex parte* communication. ECF No. 101-1, Mem. in Supp. of Mot. for Admin. Stay, at 1, 4, 6, 15. That contention is meritless; there is nothing improper in HRSA, as the regulator charged with implementing and enforcing the 340B Program, communicating with a regulated entity, and Sanofi offers nothing to suggest otherwise. Moreover, it is the appointed ADR panel—not HRSA itself—that adjudicates ADR petitions, so HRSA's communication to NACHC requesting it to refile *before* the HRSA Administrator selected panelists plainly is predicate to, and separate from, the adjudicatory proceeding.

case prevented Defendants from moving forward with NACHC's joint ADR petition." *Id.* at 3. That opportunistic revision is inaccurate; as explained in detail above, undersigned counsel repeatedly has confirmed that the process *was moving forward* as to NACHC's petition. *See supra* (discussing April 2021 public filing confirming that *NACHC*'s petition would move forward once Secretary Becerra appointed Board members). HRSA's recent decision, out of an abundance of caution, to request NACHC sever its petition so as to avoid any dispute about whether the process was moving forward as to Lilly does not change the fact that *nothing* in this litigation has remotely suggested that the *Lilly* injunction would prevent the ADR process from moving forward as to Sanofi. Given Sanofi's choice to abandon its emergency motion, over HHS's express refusal to join that request, the Court should not countenance Sanofi's newly conceived claim that it expected an injunction as to another party in another case where Sanofi is not a party to have tied the agency's hands.[3]

Third, Sanofi offers no excuse for having rushed to request emergency relief in this Court before having first asked *the ADR Panel* for the relief it seeks. Although Sanofi asserts that it faces an "obligation … to imminently respond to a pending ADR petition," the preamble to the ADR Rule explains that "[t]he ADR Panel is empowered to utilize the deadlines set forth in the Federal Rules of Civil Procedure as necessary," 85 Fed. Reg. 80,640, meaning that the panel itself can extend or even stay Sanofi's deadline. Sanofi must first exhaust before the agency, by requesting that the panel grant an extension of its deadline to answer NACHC's petition (or even an indefinite administrative stay), before leapfrogging to ask this Court to halt the administrative process. Indeed, undersigned counsel

[3] Sanofi falsely asserts that "[a]ll this time, NACHC's joint ADR petition lay dormant—as that petition named Lilly … as a defendant" until "HRSA invited NACHC to work around the preliminary injunction." Stay Mot. at 3-4. It should come as no surprise that it would take significant time and work for the agency to implement a new and complex administrative process such as the ADR Rule, but that does not indicate dormancy. And in addition to the public statements in *NACHC* quoted above, in which HHS disclosed that work on the ADR process was ongoing even after the entry of the preliminary injunction in *Lilly*, throughout the past few months undersigned counsel has conveyed to counsel for Sanofi that implementation was ongoing.

explained as much in a meet-and-confer on October 6, 2021, and Sanofi later that same day sent via email (not formal motion) a request that the ADR Panel "enter an administrative stay of Sanofi's obligation to respond" "and toll Sanofi's response deadline until 30 days after the court rules." *See* ECF No. 101-4, Shumate Email Mar. 6, 2021. But Sanofi sent that request just before eight o'clock in the evening and instructed that it would "seek emergency relief from the court if the ADR Panel is unwilling to grant an administrative stay" *in fewer than twenty-four hours*. *See id.* (requesting Panel response "no later than **4:00 PM EST on October 7, 2021**"). This arbitrary and unilaterally imposed deadline for the Panel to respond was not reasonable—particularly when unaccompanied by a motion briefing Sanofi's request for a stay. Sanofi should not be granted emergency relief by this Court without having first exhausted that request before the agency.

Fourth, Sanofi's request that this Court "stay the portion of the ADR Rule requiring Sanofi to respond to the pending ADR petition" is no more appropriate for a stay under the APA than was the last "stay" sought by Sanofi. In May 2021 Sanofi sought a "stay" of its deadline to respond to the Violation Letter issued by HRSA. *See* ECF No. 72, Mot. to Expedite and for Tem. Admin. Stay. In opposition HHS explained, *inter alia*, that the deadline Sanofi sought to forestall was simply an instruction for Sanofi to communicate with its regulator, that Sanofi could comply with that instruction or ignore it (albeit at the risk of agency penalties), and that it was not appropriate for an administrative stay. *See* ECF No. 79, Opp. to Stay. This Court agreed, finding that the deadline imposed by HRSA for Sanofi to communicate its plan to come back into statutory compliance did not cause Sanofi to "suffer any substantial prejudice if a stay is not entered." ECF No. 83, Order Denying Stay. So too here; under the ADR Rule, Sanofi should respond to NACHC's petition, but that response can come in the form of a motion to dismiss under Federal Rule of Civil Procedure 12 or even a request for an administrative stay pending resolution of this litigation.

Regardless whether the ADR Panel stays the administrative proceedings, Sanofi's deadline to

respond to the administrative petition is not the type of agency action appropriate for a stay under 5 U.S.C. § 705. That provision only allows a court "to the extent necessary to prevent irreparable injury" to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." Sanofi's status or rights will not be prejudiced by filing a motion or response before the ADR process that Congress mandated. Relatedly, Sanofi's claims of irreparable harm are meritless. Sanofi continues to base its allegations of irreparable harm solely on its constitutional challenges to the Rule, yet HHS already has briefed for the Court why such allegations do not, as a matter of law, support irreparable harm. *See* ECF No. 29 at 29-31. And the Court could not enter a stay on such grounds without deciding the merits of thorny constitutional issues, making such allegations particularly inappropriate for decision on rushed, emergency briefing.[4]

In conclusion, HHS respectfully suggests that the Court need not consider the merits of Sanofi's emergency request for the equitable and procedural reasons stated herein. Should the Court wish to consider the merits of Sanofi's original request for a preliminary injunction of the ADR Rule, however, in the interests of judicial economy, HHS incorporates by reference its prior briefing setting forth (1) why Sanofi's challenges to the ADR Rule lack merit and (2) why Sanofi has not established irreparable harm or that the balance of equities support its request. Specifically, HHS's defense of the ADR Rule can be found at pages 31-53 of HHS's memorandum in support of its motion to dismiss, *see* ECF No. 62-1, and pages 26-38 of its reply in support of that motion, *see* ECF No. 89. HHS has rebutted Sanofi's allegations of irreparable harm and the balance-of-the-equities in pages 30-35 of its

[4] Sanofi also argues that it faces imminent injury from the "threat of HHS enforcement action, including the threat of crippling civil monetary penalties and the potential loss of its ability to participate in Medicare." Stay Mot. at 12-13. But the possibility of penalties and expulsion from Medicare stem from the separate enforcement process HRSA is conducting—a process this Court already has declined to enjoin. *See* ECF No. 83; *see also* Stay Mot. 12-13 (acknowledging that Sanofi already has been referred within the agency for the possible imposition of financial penalties).

opposition to Sanofi's (later abandoned) motion for preliminary injunction, *see* ECF No. 29. Regardless whether on the merits of Sanofi's claims or on equitable grounds related to Sanofi's litigation tactics, HHS respectfully urges the Court to deny Sanofi's third emergency request and allow the agency process to proceed while the Court concludes its consideration of the parties' fully briefed dispositive motions.

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Respectfully submitted,

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